

Application No. 10/088,966

Reply to Office Action

REMARKS/ARGUMENTS*Prosecution History*

Applicants provide herein a response to the Office Action mailed May 16, 2005 in which claims 75-85 were withdrawn and claims 86-95 were rejected on various grounds.

*Amendments*

Claims 75-85 are cancelled as drawn to an unelected invention in response to a restriction requirement. Thus, with entry of the present amendment, claims 86-106 will be pending, which Applicants submit are in condition for allowance. The amended and new claims find exemplary support in the originally filed claims as well as in the specification. With the cancellation of withdrawn claims, claims dependent from such claims have been revised accordingly. No new matter has been added by the claim amendments. New claims 96 and 102 find support in cancelled claim 77; new claim 97 finds support in cancelled claim 81; new claims 99, 101, 104 and 106 find support in cancelled claims 76, 84, and 85; and new claims 98, 100, 103, and 105 find support in the specification at page 10, lines 11 and 12, and page 48 (Table 7). Applicants reserve the right to pursue any unclaimed, originally claimed, or subsequently claimed subject matter in related applications.

*Consideration of the Information Disclosure Statement*

Attached to the Office Action were copies of initialed 1449 forms listing various references. These 1449 forms had been filed along with copies of the various references with Information Disclosure Statements. While the Examiner has initialed most of the references, some of the references (AE through AH) have been crossed out. Applicants' records indicate that at least English abstracts for these foreign language references were provided, and the 1449 form submitted also indicated that such abstracts were provided. Upon request, Applicants can provide copies of what was earlier sent to the Office. Applicants respectfully request that these references be considered and an initialed 1449 form or equivalent be provided demonstrating the same.

*The Indefiniteness Rejection Has Been Rendered Moot*

Beginning at the bottom of page 2 of the Office Action, the Office rejected claims 86-95 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for use of the term

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"analogous." The claims as amended no longer recite that term. Accordingly, the indefiniteness rejection has been rendered moot and that rejection should be withdrawn.

*The Novelty Rejection Has Been Rendered Moot*

Beginning on page 3 of Office Action, the Office rejected claims 86-95 under 35 U.S.C. § 102(b), as allegedly anticipated by Mariani et al. (U.S. Patent No. 5,654,141). Applicants believe that the claim amendments have rendered this rejection moot as the rejection was premised on the allegation that Mariani et al. teaches a primer pair that is "analogous" to SEQ ID NOS: 2 and 25. Accordingly, the rejection should be withdrawn. Moreover, Mariani et al. does not disclose the use of sequences that are derived from the terminal region of the 23S rDNA gene nor sequences derived from the 23S-5S transcribed spacer region nor from the beginning of the 5S rDNA gene. There is neither an explicit nor an implicit disclosure by Mariana et al. with respect to sequences derived from the aforementioned regions.

*The Claimed Invention Is Nonobvious Over The Cited References*

Beginning at the bottom of page 4 of the Office Action, the Office rejected claims 86-95 under 35 U.S.C. § 103(a) as allegedly unpatentable over Mariani et al. in view of Yamamoto et al. (Genebank Accession No. AB001341, submitted January 25, 1997). Applicants respectfully traverse the rejection.

As is well-settled, in order to establish a *prima facie* case of obviousness with respect to a claim, at least two criteria must be met: (1) the prior art references must suggest to one of ordinary skill in the art to make the subject matter defined by the claims in issue and (2) the prior art references must provide one of ordinary skill in the art with a reasonable expectation of success in so making the subject matter defined by the claims in issue. Both the suggestion and the reasonable expectation of success must be found in the prior art references, not in the disclosure of the patent application in issue. *See, e.g., In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Further, it is well settled that the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Mariani et al. discloses methods of detecting bacteria based on detection of 16S ribosomal RNA. *See, e.g.,* at col. 2, lines 54-65, col. 4, lines 31-65, and col. 8, lines 39-56.

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In contrast, the present invention is based on the detection of nucleic acids derived from 5 S ribosomal DNA, 23 S ribosomal DNA, and the transcribed spacer between the 5 S and 23 S ribosomal DNA. See, e.g., the specification at page 7 and 8. Mariana et al. does not suggest or teach detection based on such nucleic acids.

The Yamamoto et al. reference discloses a 16,446 b.p. clone from the *E. coli* genome. In contrast, SEQ ID NOS: 2 and 25 are 20 and 18 b.p. respectively. Mariani et al. and Yamamoto et al., alone or in combination, neither teach nor suggest selecting SEQ ID NOS: 2 or 25 or any other sequence derived from 5 S, 23 S, or 5 S-23 S transcribed spacer DNA

The Buck reference (BioTechniques, 27:528-536 (1999)) is a generic study about the success of designing primers and does not remedy the deficiencies of Mariana et al. and Yamamoto et al. Success in designing primers in general does not provide a reasonable expectation of success in designing primers with particular properties such as those with a desired selectivity.

Accordingly, the Office has failed to establish a *prima facie* case of obviousness, and for this reason alone the obviousness rejection should be withdrawn. Even if the Office believes that a *prima facie* case has been established, the superior and unexpected results of the claimed invention are sufficient to rebut a *prima facie* case of obviousness. The presently claimed subject matter is based on a surprising discovery that particular sequences are suitable for identification of almost all bacterial species. See, e.g., specification page 7, lines 8-9, page 8, lines 6-14, and the Examples. In particular, SEQ ID NOS: 2 and 25 of the present application allow for a specific detection of the taxonomic unit of enterobacteria, not only of the detection of single species of that unit.

The Examiner appears to be arguing that one could try using sequences derived from Yamamoto as primers to arrive at the presently claimed subject matter. An invitation to experiment or "obvious to try" rationale is not the correct standard for judging obviousness. Moreover, the Examiner's approach as articulated in the Office Action amounts to a reconstruction that would only be possible with the use of hindsight, i.e., with the knowledge of the present application and the invention as claimed therein. It is impermissible for the Patent Office to engage in hindsight reconstruction of the claimed invention by using

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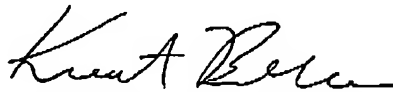
Applicants' invention as a template and selecting and combining elements from references to fill in that template. See *In re Gorman*, 933 F.2d 982, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

Accordingly, the obviousness rejection is improper and should be withdrawn.

*Conclusion*

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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